INTERNATIONAL FOOD STANDARDS



ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

CAC/GL 10-1979

Adopted in 1979. Amendment: 1983, 1991, 2009 and 2015. Revision: 2008.

1. PREAMBLE

These lists include nutrient compounds, which may be used for nutritional purposes in foods for special dietary uses intended for infants and young children in accordance with 1) the criteria and conditions of use identified below and 2) other criteria for their use stipulated in the respective standards. In addition, the sources from which the nutrient compound is produced may exclude the use of specific substances where religious or other specific dietary restrictions apply. As noted in the respective standards, their use may either be essential or optional.

2. CRITERIA FOR THE INCLUSION AND DELETION OF NUTRIENT COMPOUNDS FROM THE ADVISORY LISTS

- **2.1** Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists only if:
 - (a) they are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children
 - (b) it is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available
 - (c) the purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognised specification. If there is no internationally recognised specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered
 - (d) the stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated
 - (e) the fulfilment of the above criteria shall be demonstrated by generally accepted scientific criteria.
- 2.2 Nutrient compounds may be added to the Lists based on the criteria above. Nutrient compounds shall be deleted from the Lists if they are found no longer to meet the above criteria. If a country proposes to add or delete a nutrient compound to/from a list, the country should provide information that addresses how the nutrient compound satisfies/does not satisfy the criteria in Section 2.1.

3. OPTIONAL INGREDIENTS

The Optional Ingredients sections in Codex standards for foods for infants and young children do not identify all optional ingredients that may be considered for use in foods for special dietary uses intended for infants and young children. Optional ingredients added for nutritional purposes to foods for special dietary uses intended for infants and young children should meet the criteria specified in Section 2.1. They should also meet the provisions for optional ingredients in the respective Codex standard for foods for infants and young children.

A: ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Req	uirements by		A		Codex Food to Infants and	d Standards d Young Child	ren
	CAC ¹	International and/ or national bodies	IF		FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young
			Sec. A ²	Sec. B ³				children
1. Source of Calcium (Ca)							
1.1 Calcium carbonate	√ (1981)	JECFA (1973), Ph Int, FCC, USP, NF, Ph Eur, BP, DAB	V	√	V	V	√	√
1.2 Calcium chloride	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, JP, BP, DAB	√	√	√	√	V	V
1.3 Tricalcium dicitrate (Calcium citrate)	√ (1979)	JECFA (1975), FCC, USP, DAC	√	√	√	√	√	V
1.4 Calcium gluconate	√ (1999)	JECFA (1998), Ph Int, FCC, USP, Ph Eur, BP, DAB	V	V	V	V	V	V
1.5 Calcium glycerophosphate		FCC, Ph Eur, Ph Franc	√	√	√	√	√	V
1.6 Calcium L-lactate	√ (1978)	JECFA (1974), FCC, USP, Ph Eur (tri- and penta-hydrate), BP, DAB	V	√	V	V	V	√

¹ CAC

= Codex Alimentarius Commission

= Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

= Follow-up Formula

² IF Sect. A ³ IF Sect. B ⁴ FUF ⁵ PCBF

= Processed Cereal Based Food for Infants and Young Children

= Canned Baby Food

⁶ CBF ⁷ FSMP

= Food for Special Medical Purposes other than Infant Formula

Nutrient Source	Purity Req	uirements by		A		Codex Food to Infants and	Standards I Young Child	ren
	CAC ¹	International and/ or national bodies		IF	FUF ⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young
			Sec. A ²	Sec. B ³				children
1.7 Calcium hydroxide	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP	V	V	V	√	√	√
1.8 Calcium oxide	√ (1979)	JECFA (1975), FCC, DAC	-	\checkmark	-	√	√	V
1.9 Calcium dihydrogen phosphate (Calcium phosphate, monobasic)	√ (1997)	JECFA (1996), Ph Int, FCC	√	V	V	٧	√	V
1.10 Calcium hydrogen phosphate (Calcium phosphate, dibasic)	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP, DAB	V	V	√	√	V	V
1.11 Tricalcium diphosphate (Calcium phosphate, tribasic)		JECFA (1973), Ph Int, FCC, BP	7	V	1	V	V	V
1.12 Calcium sulphate	√ (1979)	JECFA (1975), Ph Int, FCC, Ph Eur (dihydrate), DAB	-	V	-	-	-	V
		2.	Source of	Iron (Fe)				
2.1 Ferrous carbonate, stabilised with saccharose		DAB	-	V	-	√	V	V
2.2 Ferrous fumarate		Ph Int, FCC, USP, Ph Eur, BP	√	V	√	V	√	√
2.3 Ferrous gluconate	√ (2001)	JECFA (1999), FCC, USP, Ph Eur, DAB, BP	V	V	V	√	√	√
2.4 Ferrous lactate	√ (1991)	JECFA (1989), FCC, NF	V	V	√	√	√	V

Nutrient Source	Purity Req	uirements by	Use in Codex Food Standards Applicable to Infants and Young Children					ren
	CAC ¹	International and/ or national bodies		IF	FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young
			Sec. A ²	Sec. B ³				children
2.5 Ferrous sulphate	√ (2001)	JECFA (1999), Ph Int, FCC, USP, Ph Eur, BP, DAB	V	√	V	V	V	√
2.6 Ferric ammonium citrate	√ (1987)	JECFA (1984), FCC, DAC	V	√	√	V	√	V
2.7 Ferric citrate		FCC	√	√	√	√	√	√
2.8 Ferric diphosphate (pyrophosphate)		FCC	V	√	V	√	√	V
2.9 Hydrogen reduced iron		FCC, DAB	-	√	-	√	√	V
2.10 Electrolytic iron		FCC	-	V	-	V	√	V
2.11 Carbonyl iron		FCC	-	V	-	V	√	V
2.12 Ferric saccharate		Ph Helv, DAB, ÖAB	-	V	-	V	V	V
2.13 Sodium ferric diphosphate		FCC	-	√	-	V	√	√
2.14 Ferrous citrate		FCC	√	√	√	√	√	√
2.15 Ferrous succinate		MP, MI	V	V	√	V	√	√
2.16 Ferrous bisglycinate		JECFA (2003)	V	√	V	√	V	√

Nutrient Source	Purity Req	uirements by		Use in Codex Food Standards Applicable to Infants and Young Children				
	CAC ¹	International and/ or national bodies		IF	FUF⁴	PCBF⁵	CBF ⁶	FSMP ⁷ for infants and young
			Sec. A ²	Sec. B ³				children
2.17 Ferric orthophosphate		FCC	-	-	-	V	-	-
3. Source of Magnesiu	m (Mg)		•				·	
3.1 Magnesium hydroxide carbonate		JECFA (1979), USP, BP, DAB	√	V	√	√	√	√
3.2 Magnesium chloride	√ (1979)	JECFA (1979), FCC, USP, Ph Eur (-4,5-hydrate), BP, DAB	√	√	V	√	√	V
3.3 Magnesium gluconate	√ (2001)	JECFA (1998), FCC, DAC	√	V	√	V	V	V
3.4 Magnesium glycero-phosphate		Ph Eur, BPC	-	V	-	V	V	V
3.5 Magnesium hydroxide	√ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	V	√ 	√	√	V
3.6 Magnesium lactate	√ (1987)	JECFA (1983) (Mg-DL- Lactate, Mg-L-Lactate)	-	V	-	V	V	V
3.7 Magnesium oxide		JECFA (1973), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	√	√ 	√	√	√
3.8 Magnesium hydrogen phosphate (Magnesium phosphate, dibasic)	√ (1985)	JECFA (1982), FCC, DAB	٧	V	√	V	V	V
3.9 Trimagnesium phosphate (Magnesium phosphate, tribasic)	√ (1981)	JECFA (1982), FCC	V	V	√	٧	V	V

Nutrient Source	Purity Req	uirements by		Α		Codex Food to Infants and	l Standards d Young Child	ren
	CAC ¹	International and/ or national bodies		IF	FUF⁴	PCBF⁵	CBF ⁶	FSMP ⁷ for infants and young
			Sec. A ²	Sec. B ³	·······			children
3.10 Magnesium sulphate		Ph Eur (heptahydrate), FCC, USP, JP, BP, DAB, DAC	V	V V	V	V	√	
3.11 Magnesium acetate		Ph Eur, DAC	-	√	-	-	-	V
3.12 Magnesium salts of citric acid		USP, DAC	V	√	√	√	√	V
3.13 Magnesium carbonate		JECFA (1973), FCC, USP, Ph Eur, BP, DAB	V	√	V	V	V	V
4. Source of Sodium (Na)							
4.1 Sodium carbonate	√ (1979)	JECFA (1975), FCC, USP, NF, Ph Eur, BP, DAB	٧	V	√	-	-	√
4.2 Sodium hydrogen carbonate (Sodium bicarbonate)	√ (1979)	JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	V	V	V	-	-	√
4.3 Sodium chloride		Ph Int, FCC, USP, Ph Eur, JP, BP, DAB	√	√	√	-	-	√
4.4 Trisodium citrate (Sodium citrate)		JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	V	V	V	-	-	V
4.5 Sodium gluconate	√ (1999)	JECFA (1998), FCC, USP, DAC	√	√	√	-	-	√
4.6 Sodium L-lactate	√ (1978)	JECFA (1974), FCC, USP, Ph Eur, BP, DAB	V	V	√	-	-	V
4.7 Sodium dihydrogen phosphate (Sodium phosphate, monobasic)	√ (1995)	JECFA (1963), FCC, USP, Ph Eur (dihydrate)	V	V	V	-	-	√

Nutrient Source	Purity Req	uirements by		Use in Codex Food Standards Applicable to Infants and Young Children IF FUF ⁴ PCBF ⁵ CBF ⁶ FSMP ⁷ for infants and young children				
	CAC ¹	International and/ or national bodies		IF	FUF⁴	PCBF ⁵	CBF ⁶	
			Sec. A ²	Sec. B ³				
4.8 Disodium hydrogen phosphate (Sodium phosphate, dibasic)		JECFA (1975), Ph Int, FCC, USP, BP	√	٧	√	-	-	V
4.9 Trisodium phosphate (Sodium phosphate, tribasic)		JECFA (1975), FCC, DAC	√	√	V	-	-	V
4.10 Sodium hydroxide	√ (1979)	JECFA (1975), Ph Int, FCC, USP, NF, Ph Eur, JP, BP, DAB	√	V	V	-	-	V
4.11 Sodium sulphate		JECFA (2000), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	V	V	-	-	√
5. Source of Potassiu	m (K)							
5.1 Potassium carbonate	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, DAC	V	V	V	-	-	V
5.2 Potassium hydrogen carbonate (Potassium bicarbonate)	√ (1979)	JECFA (1975), FCC, USP, Ph Eur, BP, DAB	V	V	√	-	-	V
5.3 Potassium chloride	√ (1983)	JECFA (1979), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	V	V	√	V	V
5.4 Tripotassium citrate (Potassium citrate)		JECFA (1975), Ph Int, FCC, USP, Ph Eur, BP, DAB	√	V	V	V	√	V
5.5 Potassium gluconate	√ (1999)	JECFA (1998), FCC, USP, DAC	√	$\sqrt{}$	√	V	V	V

Nutrient Source	Purity Req	uirements by		A		Codex Food Infants and	Standards Young Childr	en	
	CAC ¹	International and/ or national bodies	IF		FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young	
			Sec. A ²	Sec. B ³				children	
5.6 Potassium glycero-phosphate		FCC	-	V	-	V	√	V	
5.7 Potassium L- lactate	√ (1978)	JECFA (1974), FCC, DAB	√	V	√	V	V	V	
5.8 Potassium dihydrogen phosphate (Potassium phosphate, monobasic)	√ (1979)	JECFA (1982), FCC, NF, Ph Eur, BP, DAB	V	V	V	-	-	V	
5.9 Dipotassium hydrogen phosphate (Potassium phosphate, dibasic)	√ (1979)	JECFA (1982), FCC, BP	√	V	V	-	-	V	
5.10 Potassium phosphate, tribasic	√ (1979)	JECFA (1982)	√	√	√	-	-	V	
5.11 Potassium hydroxide	√ (1979)	JECFA (1975), FCC, NF, Ph Eur, JP, BP, DAC	V	V	√	-	-	V	
6. Source of Copper (Cu)				•				
6.1 Cupric gluconate (Copper gluconate)		FCC, USP	√	√	√	√	√	√	
6.2 Cupric sulphate (Copper sulphate)	√ (1981)	JECFA (1973), FCC, USP, Ph Eur, DAB	√	V	√	V	V	V	
6.3 Cupric carbonate		MI	√	√	√	√	√	V	
6.4 Cupric citrate		FCC, USP	V	V	√	√	V	V	

Nutrient Source	Purity Req	uirements by		A		Codex Food to Infants and	Standards Young Child	ren		
	CAC ¹	International and/ or national bodies	IF		FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young		
			Sec. A ²	Sec. B ³				children		
7. Source of lodine (I)										
7.1 Potassium iodide		Ph Int, FCC, USP, Ph Eur, BP, DAB	√	V	√	√	V	V		
7.2 Sodium iodide		Ph Eur, USP, BP, DAB	V	V	√	V	√	√		
7.3 Potassium iodate	√ (1991)	JECFA (1988), FCC	√	$\sqrt{}$	√	V	V	V		
7.4 Sodium iodate		FCC	-	V	-	√	V	√		
8. Source of Zinc (Zn)		1		1	1	1	-		
8.1 Zinc acetate		USP, Ph Eur (dihydrate)	V	V	√	V	V	√		
8.2 Zinc chloride		USP, Ph Eur, JP, BP, DAB	√	V	√	√	√	√		
8.3 Zinc gluconate		FCC, USP, DAC	√	$\sqrt{}$	√	V	V	V		
8.4 Zinc lactate		FCC	√	$\sqrt{}$	√	√	√	√		
8.5 Zinc oxide		Ph Int, FCC, USP, Ph Eur, BP, DAB	V	$\sqrt{}$	√	V	V	√		
8.6 Zinc sulphate		FCC, USP, Ph Eur, BP	V	V	√	√	V	√		
8.7 Zinc carbonate		USP, BP (hydroxide carbonate)	-	$\sqrt{}$	-	-	-	V		
8.8 Zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate)		USP	√ ·	V	V	V	√	V		

Nutrient Source	Purity Re	equirements by		A		Codex Food to Infants and	d Standards d Young Child	lren
	CAC ¹	International and/ or national bodies	IF		FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young
			Sec. A ²	Sec. B ³				children
9. Source of Mangane	ese (Mn)			l				-
9.1 Manganese(II) chloride		FCC	√	√	V	√	V	V
9.2 Manganese(II) citrate		FCC	V	√	√	√	V	V
9.3 Manganese(II) glycero-phosphate		FCC	-	√	-	√	V	V
9.4 Manganese(II) sulphate		FCC, USP, Ph Eur (monohydrate)	V	√	√	√	V	V
9.5 Manganese(II) gluconate		FCC	V	√	√	√	V	V
9.6 Manganese(II) carbonate		MI	√	√	V	√	V	V
10. Source of Seleniu	ım (Se)	·						·
10.1 Sodium selenate		MI	V	√	V	V	-	√
10.2 Sodium selenite		Ph Eur, USP, MP, MI	√	√	V	√	-	V
10.3 Sodium hydrogen selenite		DVFA	-	V	-	-	-	V

Nutrient Source	Purity Re	equirements by		A		Codex Food to Infants and	Standards I Young Childr	en
	CAC ¹	International and/ or national bodies		IF	FUF ⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young children
			Sec. A ²	Sec. B ³				
11. Chromium (Cr III)	•				•	•	•	
11.1 Chromium (III) sulphate		USP, MI	-	V	-	-	-	V
11.2 Chromium (III) chloride		USP, MI	-	$\sqrt{}$	-	-	-	V
12. Molybdenum (Mo	VI)	•						
12.1 Sodium molybdate		Ph Eur (dihydrate), BP, DAB	-	$\sqrt{}$	-	-	-	√
12.2 Ammonium molybdate		FCC, USP	-	V	-	-	-	V
13. Fluoride (F)						<u> </u>		
13.1 Sodium fluoride		FCC, USP, Ph Eur, BP, DAB	-	V	-	-	-	√
13.2 Potassium fluoride		FCC, DAB	-	V	-	-	-	√
13.3 Calcium fluoride		DAB	-	V	-	-	-	√

B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Req	uirements by				ex Food Stants and Yo		ren
	CAC ¹	International and/or national bodies	IF		FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and
			Sec. A ²	Sec. B ³				young children
1. Vitamin A								
1.1 all trans Retinol		FCC (vitamin A), USP, Ph Eur (vitamin A)	V	V	√	√	V	√
1.2 Retinyl acetate		FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan	V	V	V	√	V	V
1.3 Retinyl palmitate		FCC (vitamin A), USP, Ph Eur (vitamin A), Jap Food Stan	V	√	V	V	V	V
2. Provitamin A								
2.1 Beta-Carotene	√ (1991)	JECFA (1987), FCC, USP, Ph Eur, Jap Food Stan	V	√	V	V	V	V
3. Vitamin D	•				•			•
3.1 Vitamin D ₂ = Ergocalciferol		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	V	V	√	V	V	√
3.2 Vitamin D ₃ = Cholecalciferol		Ph Int, FCC, USP, Jap Food Stan, BP, DAB	V	V	V	V	V	V

¹ CAC = Codex Alimentarius Commission

² IF Sect. A Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

³ IF Sect. B Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

⁴ FUF FOLSE FO

⁶ CBF ⁷ FSMP = Canned Baby Food

⁼ Food for Special Medical Purposes other than Infant Formula

Nutrient Source	Purity Req	uirements by				lex Food St ants and Yo		ren FSMP ⁷ for infants and young children			
Marient Godise	CAC ¹	International and/or national bodies	I	F	FUF⁴	PCBF ⁵	CBF ⁶				
			Sec. A ²	Sec. B ³							
4. Vitamin E											
4.1 D-alpha-Tocopherol	√ (2001)	JECFA (2000), FCC, USP, NF, Ph Eur	V	√	√	V	V	V			
4.2 DL-alpha-Tocopherol	√ (1989)	JECFA (1986), FCC, USP, NF, Ph Eur, Jap Food Stan	$\sqrt{}$	V	√	√	V	V			
4.3 D-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur	√	√	√	√	√	√			
4.4 DL-alpha-Tocopheryl acetate		FCC, USP, NF, Ph Eur, BP	V	√	√	√	V	V			
4.5 D-alpha-Tocopheryl acid succinate		FCC, USP, Ph Eur	-	√	-	-	-	V			
4.6 DL-alpha-Tocopheryl acid succinate		NF, MP, MI, USP, Ph Eur	-	√	-	-	-	V			
4.7 DL-alpha-Tocopheryl polyethylene glycol 1000 succinate		FCC, USP	-	V	-	-	-	V			
5. Vitamin C	·L				I.	<u> </u>					
5.1 L-Ascorbic acid	√ (1981)	JECFA (1973), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	V	V	V	√	V	V			
5.2 Calcium-L-ascorbate	√ (1983)	JECFA (1981), FCC, USP, Ph Eur	V	√	√	√	V	√			
5.3 6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate)		JECFA (1973), FCC, USP, NF, Ph Eur, Jap Food Stan, BP, DAB	V	V	V	V	V	V			
5.4 Sodium-L-ascorbate		JECFA (1973), FCC, USP, Ph Eur, Ph Franc, Jap Food Stan, DAC	V	V	V	V	V	V			
5.5 Potassium-L-ascorbate		FCC	√	√	√	√	V	V			

Nutrient Source	Purity Req	Use in Codex Food Standards Applicable to Infants and Young Children						
Nutrient Course	CAC ¹	International and/or national bodies	II.	F	FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and
			Sec. A ²	Sec. B ³				young children
6. Vitamin B ₁								
6.1 Thiaminchloride hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	V	V	V	V	V	√
6.2 Thiamin mononitrate		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	V	$\sqrt{}$	√	√	\checkmark	V
7. Vitamin B ₂					1	1		
7.1 Riboflavin	√ (1991)	JECFA (1987), Ph Int, FCC, USP, Ph Eur, JP, Jap Food Stan, BP, DAB	V	V	√	V	V	V
7.2 Riboflavin-5'-phosphate sodium	√ (1991)	JECFA (1987), USP, Ph Eur, JP, Jap Food Stan, BP, DAB	V	√	V	V	V	V
8. Niacin								
8.1 Nicotinic acid amide (Nicotinamide)		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB	V	V	V	√	V	V
8.2 Nicotinic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, BP, DAB	V	V	V	√	V	V
9. Vitamin B ₆								
9.1 Pyridoxine hydrochloride		Ph Int, FCC, USP, Ph Eur, Jap Food Stan, DAB	V	V	V	V	√	V
9.2 Pyridoxal 5-phosphate		MI, FCC, USP	√	V	√	√	V	√
10. Folic acid	•				•	- '		
10.1 N-Pteroyl-L-glutamic acid		Ph Int, FCC, USP, Ph Eur, Jap Food Stan	V	V	V	V	V	V
10.2 Calcium-L-methyl-folate		JECFA (2005)	-	V	-		-	√

Nutrient Source	Purity Requirements by		Use in Codex Food Standards Applicable to Infants and Young Children						
Numeric Course	CAC ¹	International and/or national bodies	IF		FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and	
			Sec. A ²	Sec. B ³				young children	
11. Pantothenic acid									
11.1 Calcium-D-pantothenate		FCC, USP, Ph Eur, Jap Food Stan, DAB	√	V	V	√	V	V	
11.2 Sodium-D-pantothenate		Jap Food Stan, DAB	V	√	√	V	V	√	
11.3 D-Panthenol/		FCC, USP, Ph Eur	V	V	V	V	V	√	
11.4 DL-Panthenol		FCC, USP, Ph Eur	V	√	√	V	V	√	
12. Vitamin B ₁₂									
12.1 Cyanocobalamin		Ph Int, FCC, USP, Ph Eur, BP, DAB	V	V	V	V	V	V	
12.2 Hydroxo-cobalamin		Ph Int, USP, NF, Ph Eur (hydro-chloride)	V	V	$\sqrt{}$	√	V	V	
13. Vitamin K ₁									
13.1 Phytomenadione (2-Methyl-3-phytyl-1,4- naphthoquinone/ Phylloquinone/ Phytonadione)		Ph Int, FCC (<u>vitamin K</u>), USP, Ph Eur, BP	V	V	V	√	V	٨	
14. Biotin									
14.1 D-Biotin		FCC, USP, Ph Eur	V	V	V	V	V	V	

: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by ent Source			Use in Codex Food Standards Applicable to Infants and Young Children						
	CAC ¹	International and/or national bodies	IF		FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young children		
			Sec. A ²	Sec. B ³						
1. Amino acids ⁸										
1.1 L-Arginine		FCC, USP, Ph Eur, BP, DAB		$\sqrt{}$				√		
1.2 L-Arginine hydrochloride		FCC, USP, Ph Eur, BP, DAB		V			√			
1.3 L-Cystine		FCC, USP, Ph Eur		V	1			√		
1.4 L-Cystine dihydrochloride		MI		√				√		
1.5 L-Cysteine		DAB	only for improving the nutritional quality	√				√		
1.6 L-Cysteine hydrochloride		FCC, Ph Eur	of the protein	√	only for im	proving the nut of the protein		√		
1.7 L- Histidine		FCC, USP, Ph Eur, DAB	(when the protein is nutritionally	√		the protein is n	utritionally	√		
1.8 L- Histidine hydrochloride		FCC, Ph Eur, DAB	inadequate for its intended use)	√	inadeq	uate for its inte	naea use)	√		
1.9 L-Isoleucine		FCC, USP, Ph Eur, DAB	internace accy	√				√		
1.10 L-Isoleucine hydrochloride		FCC, USP		√				√		
1.11 L-Leucine		FCC, USP, Ph Eur, DAB		√				√		
1.12 L-Leucine hydrochloride		MI, FCC, USP		√		√				

¹ CAC = Codex Alimentarius Commission

² IF Sect. A = Section A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants ³ IF Sect. B = Section B of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

⁼ Follow-up Formula

⁴ FUF ⁵ PCBF = Processed Cereal Based Foods for Infants and Young Children

⁶ CBF = Canned Baby Food

⁷ FSMP = Food for Special Medical Purposes other than Infant Formula

⁸ As far as applicable, also the free, hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids may be used for FSMP.

Nutrient Source	Р	urity Requirements by	Use in Codex Food Standards Applicable to Infants and Young Children						
ruanisin sounss	CAC ¹	International and/or national bodies	IF		FUF ⁴ PCBF ⁵ CBF		CBF ⁶	FSMP ⁷ for infants and young children	
			Sec. A ²	Sec. B ³					
1.13 L-Lysine		USP		√				√	
1.14 L-Lysine monohydrochloride		FCC, USP, Ph Eur, DAB	only for improving	√		√			
1.15 L-Methionine		Ph Int, FCC, USP, Ph Eur, DAB	the nutritional quality of the protein (when the protein is	√	only for i	V			
1.16 L-Phenylalanine		FCC, USP, Ph Eur	nutritionally	V	quality of the protein (when the protein is nutritionally inadequate for its intended use) √				
1.17 L-Threonine		FCC, USP, Ph Eur, DAB	inadequate for its intended use)	V					
1.18 L-Tryptophan		FCC, USP, Ph Eur, DAB	interided use)	V				V	
1.19 L-Tyrosine		FCC, USP, Ph Eur, DAB		√				V	
1.20 L-Valine		FCC, USP, Ph Eur, DAB		√				V	
1.21 L-Alanine		FCC, USP, Ph Eur, DAB	-	√	-	-	-	V	
1.22 L-Arginine-L-aspartate		Ph Eur	-	V	-	-	-	√	
1.23 L-Aspartic acid		FCC, USP, Ph Eur	-	V	-	-	-	√	
1.24 L-Citrulline		USP, DAC	-	V	-	-	-	√	
1.25 L- Glutamic acid		JECFA (1987), FCC, USP, Ph Eur	-	V	-	-	-	√	
1.26 L-Glutamine		FCC, USP, DAB	-	V	-	-	-	√	
1.27 Glycine		FCC, USP, Ph Eur	-	V	-	-	-	√	
1.28 L-Ornithine		MI, FCC	-	√	-	-	-	V	

Nutrient Source	Purity Requirements by Nutrient Source		Use in Codex Food Standards Applicable to Infants and Young Children						
144110111 6541100	CAC ¹	International and/or national bodies	IF		FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young children	
			Sec. A ²	Sec. B ³					
1.29 L-Ornithine monohydrochloride		DAB	-	√	-	-	-	√	
1.30 L-Proline		FCC, USP, Ph Eur, DAB	-	√	-	-	-	V	
1.31 L-Serine		USP, Ph Eur, DAB	-	√	-	-	-	V	
1.32 N-Acetyl-L-cysteine		USP, Ph Eur, DAB	-	√	-	-	-	V	
1.33 N-Acetyl-L-methionine		FCC	-	-	-	-	-	√ not for infants	
1.34 L-Lysine acetate		FCC, USP, MP; Ph Eur	-	√	-	-	-	V	
1.35 L-Lysine L-Aspartate		Jap Food Stan	-	√	-	-		V	
1.36 L-Lysine L-glutamate dihydrate		Jap Food Stan	-	√	-	-	-	V	
1.37 Magnesium L- aspartate		Ph Eur	-	√	-	-	-	V	
1.38 Calcium L-glutamate	√ 1991	JECFA, FCC, Jap Food Stan	-	√	-	-	-	√	
1.39 Potassium L- glutamate		JECFA, FCC, Jap Food Stan	-	√	-	-	-	√	

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Purity Requirements by Nutrient Source		Use in Codex Food Standards Applicable to Infants and Young Children						
Nutrient Source	CAC ¹	International and/or national bodies	IF		FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young children
			Sec. A ²	Sec. B ³				
2. Carnitine								
2.1 L-Carnitine		FCC, USP, Ph Eur	√	√	V	√	V	V
2.2 L-Carnitine hydrochloride		FCC	V	√	√	√	V	√
2.3 L-Carnitine tartrate		FCC, Ph Eur	V	√	V	-	-	V
3. Taurine								
3.1 Taurine		USP, JP	$\sqrt{}$	√	V	-	-	√
4. Choline								
4.1 Choline		FCC, USP	V	√	V	V	V	√
4.2 Choline chloride		FCC, DAC, DAB	V	√	√	√	V	V
4.3 Choline citrate		NF	$\sqrt{}$	√	√	√	V	√
4.4 Choline hydrogen tartrate		DAB	V	√	V	√	V	V
4.5 Choline bitartrate		FCC, NF, DAB	V	√	√	V	V	√
5. Inositols								
5.1 Myo-Inositol (=meso-Inositol)		FCC, DAC	V	V	V	V	V	√

Nutrient Source	Р	urity Requirements by	Use in Codex Food Standards Applicable to Infants and Young Children						
Numerin Source	CAC ¹ International and/or national bodies		IF		FUF⁴	PCBF ⁵	CBF ⁶	FSMP ⁷ for infants and young children	
		***************************************	Sec. A ²	Sec. B ³					
6. Nucleotides									
6.1 Adenosine 5-mono- phosphate (AMP)		FSANZ	V	√	V	-	-	√	
6.2 Cytidine 5-mono- phosphate (CMP)		FSANZ, Jap Food Stan	$\sqrt{}$	V	V	-	-	V	
6.3 Guanosine 5-mono- phosphate (GMP)		JECFA (1985)	$\sqrt{}$	V	V	-	-	V	
6.4 Inosine 5-monophos- phate (IMP)		JECFA (1974)	V	V	V	-	-	V	
6.5 Disodium Uridine 5- monophosphate salt		FSANZ, Jap Food Stan	V	√	V	-	-	V	
6.6 Disodium Guanosine 5- monophosphate salt		FCC, JECFA, FSANZ, Jap Food Stan	V	√ ·	V	-	-	√	
6.7 Disodium Inosine 5- monophosphate salt		FCC, JECFA, FSANZ, Jap Food Stan	V	√	V	-	-	√	

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations, e.g. gum arabic coated products, dry rubbed preparations. For this purpose, the food additives included in the respective specific Codex standard may be used. In addition, the following food additives may be used as nutrient carriers:

INS n.°	Additive/ Carrier	Maximum Level in Ready-to-use Food for infants and young children (mg/kg)
414	Gum Arabic (gum acacia)	10
551	Silicon dioxide	10
421	Mannitol (for vitamin_B ₁₂ dry rubbing, 0,1% only)	10
1450	Starch sodium octenyl succinate	100
301	Sodium L-ascorbate (in coating of nutrient preparations containing polyunsaturated fatty acids)	75

Abbreviations:

BP	=	British Pharmacopoeia
BPC	=	British Pharmaceutical Codex
DAB	=	Deutsches Arzneibuch
DAC	=	Deutscher Arzneimittel-Codex
DVFA	=	Danish Veterinary and Food Administration
FCC	=	Food Chemicals Codex
FSANZ	=	Food Standards Australia New Zealand
FU	=	Farmacopoea Ufficiale della Republica Italiana
JP	=	The Pharmacopeia of Japan
Jap Food Stan	=	Japanese Food Standard
MI	=	Merck Index
MP		
1711	=	Martindale Pharmacopoeia
ÖAB	=	Martindale Pharmacopoeia Österreichisches Arzneibuch
		'
ÖAB	=	Österreichisches Arzneibuch
ÖAB Ph Eur	=	Österreichisches Arzneibuch Pharmacopoeia Europaea
ÖAB Ph Eur Ph Franç	= = =	Österreichisches Arzneibuch Pharmacopoeia Europaea Pharmacopée Française